

REMARKS

Amendments to the specification:

The examiner has objected to the amendment to the specification filed February 8, 2001 on the grounds that the amendment added new matter. Applicants respectfully disagree. Applicants acknowledge that the specification, on page 22 line 27 lists the abbreviation for polyaspartic acid as PAA. As noted on the attached declaration, this notation is a typographical error and is inconsistent with the abbreviation for polyaspartic acid listed on page 6 line 26 and page 26 line 4. Applicants request that page 22 line 27 of the specification be amended to correct this typographical error.

As also noted in the attached declaration, polyacrylic acid was in fact the polymer used in the experiment described in example 6 of the specification. Applicants have attached copies of the original notebook pages containing this experiment. Notebook pages indicating the abbreviations used for polyaspartic acid and polyacrylic acid have also been provided. In light of the arguments and the declaration, Applicants request reconsideration of the objection to the amendment to the specification.

Rejection of the claims under 35 U.S.C. §112:

Claims 1 and 3-7 have been rejected under 35 U.S.C. 112, first paragraph, for reciting “the complex” without antecedent basis. Applicants have amended claim 1 to replace the term compound in step b) with the term composition, which has proper antecedent basis.

Rejection of the claims under 35 U.S.C. §103:

Claims 1, 3, and 6 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Curiel et al (US Patent 5,547,932) in view of Lee et al (WO 97/00965), taken with the evidence of Dominguez (US Patent 4,049,595). Applicants have amended claim 1 to obviate the rejection. Specifically, Applicants have amended claim 1 to incorporate the limitations of claim 4. Claim 4 has been canceled.

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Amendment dated April 18, 2005
Reply to Office action March 9, 2005

The Examiner's objections and rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendments and arguments, it is submitted that claims 1, 3 and 5-8 should be allowable. Applicants respectfully request a timely Notice of Allowance be issued in the case.

Respectfully submitted,



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I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as express mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date: 4/19/05.



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that modification of polyanion in triple complex also significantly enhances salt and serum stability.

In another preferred embodiment a polyanion used for charge reversal is cleavable. One can imagine two ways to design a cleavable polyion: 1. A polyion cleavable in backbone, 2. A polyion cleavable in side chain. First scenario would comprise monomers linked by labile bonds such as disulfide, diols, diazo, ester, sulfone, acetal, ketal, enol ether, enol ester, imine and enamine bonds. Second scenario would involve reactive groups (i.e. electrophiles and nucleophiles) in close proximity so that reaction between them is rapid. Examples include having carboxylic acid derivatives (acids, esters and amides) and alcohols, thiols, carboxylic acids or amines in the same molecule reacting together to make esters, thiol esters, anhydrides or amides. In one specific preferred embodiment the polyion contains an ester acid such as citraconic acid, or dimethylmaleyl acid that is connected to a carboxylic, alcohol, or amine group on the polyion.

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Cleavable means that a chemical bond between atoms is broken. Labile also means that a chemical bond between atoms is breakable. Crosslinking refers to the chemical attachment of two or more molecules with a bifunctional reagent. A bifunctional reagent is a molecule with two reactive ends. The reactive ends can be identical as in a homobifunctional molecule, or different as in a heterobifunctional molecule.

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Examples

Example 1

25 Materials. Plasmid DNA (pCILuc) used for the condensation studies was provided by Bayou Biolabs, Harahan, LA. Poly-L-lysine (PLL) (MW 34 kDa), poly-L-aspartic acid ([[PAA]] pAsp) (MW 36 kDa), poly-L-glutamic acid (PLG) (MW 49 kDa) and rhodamine B isothiocyanate were products of Sigma (St. Louis, MO). Polymethacrylic acid (PMA), metrizamide and fluoresceine isothiocyanate were from Aldrich (Milwaukee, WI). LabelIT kits (Mirus Corp., Madison, WI) were used for covalent labeling DNA with fluorescein and rhodamine.